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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,375	03/14/2001	Shaorong Liu	PB0006	3335

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AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
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PISCATAWAY, NJ 08855

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,375

Applicant(s)

LIU, SHAORONG

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of February 01, 2005 does not render the application allowable. Applicant has canceled claims 1-20 and added new claims 21-25 that "correspond strictly to the claims the Examiner found allowable in an earlier Office action dated May 17, 2004, including all the limitations from the now cancelled independent claims the new claims depend upon." However, a subsequent Office action dated November 04, 2004 cited new art (Mathies and Zanzucchi) which are relevant to the currently pending claims and which Applicant has not distinguished from the claimed invention.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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3. Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al. (US 6,623,613 B1) and Zanzucchi et al. (US 5,755,942). Note that for Mathies the examiner relies upon priority from the provisional application 60/157,299.

Addressing claim 21, Mathies discloses a shaped microfluidic capillary array electrophoresis chip comprising

a planar substrate (40) having a first major surface defining converging first and second elongate separation channels;

wherein each said separation channel extends between an associated cathode port (45) and an anode port (43) defined by said first major surface,

wherein said substrate further comprises a plurality of separation channel groups, wherein each said separation channel group includes a grouped pair of elongate separation channels (42) extending in fluid communication between a common cathode port (45) and anode port (43), wherein each separation channel of said grouped pair of separation channels further includes a loading segment (segment extending from either sample well 41), whereby said first major surface further defines an associated group sample port (41) and a group waste port (44) for each separation channel of said grouped pair of separation channels wherein each associated group sample port and group waste port are in fluid communication across said loading segment of a single separation channel (Figure 4 inset).

Mathies does not disclose a first perimetrical edge segment extending substantially along said first separation channel, and a second perimetrical edge segment extending substantially along said second separation channel.

Zanzucchi discloses a method for forming a shaped capillary array electrophoresis chip having a first perimetrical edge segment extending along a first separation channel and a second perimetrical edge segment extending along the last separation channel in the chip (see module 148 in Figure 7B and the unlabeled module in Figure 10 and col. 6, ll.14-50).

It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the chip shown in Figure 4 of Mathies made of 4 modules (quadrants) each having a perimetrical edge extending along a first separation channel and a second perimetrical edge extending along a second separation channel as taught by Zanzucchi in the invention of Mathies because then several sets of separations may be performed simultaneously under different conditions. For example, the modules can each be made from a different substrate material (col. 2, ll. 24-27 in Mathies) and wells and channels can be configured in each module so that each module is appropriately suited for a different assay/analysis (col. 2, ll. 20-37 and col. 5, ll. 25-37 in Zanzucchi).

Addressing claim 22, in Mathies as modified by Zanzucchi each separation channel group extends in fluid communication from a common anode port. See col. 4:62-65. However, barring evidence to the contrary, such as unexpected results, this is only an intended use limitation that does not further structurally limit the claim except for requiring an electrode at a common port because whether an electrode is an anode or a cathode is intended use, which depends on the polarity of the applied voltage. In addition, it would have been obvious to one with ordinary skill in the art at the time of the invention to reverse the cathode and anode in

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Mathies as modified by Zanzucchi if this will draw the charged analytes down the separation channels.

Addressing claim 23, Mathies discloses a method for forming a shaped capillary array electrophoresis chip comprising the steps of

providing a substantially planar substrate (40) having a first major surface (implied by Figure 4);

forming first and second converging elongate separation channels (42) in said first major surface (implied by Figure 4, which shows first and second converging channels as claimed);

forming a plurality of converging elongate separation channel groups in said first major surface, wherein each of said separation channel group includes a grouped pair of elongate separation channels extending in fluid communication between a common cathode port (45) and anode port (43), wherein each separation channel of said grouped pair of separation channels further includes a loading segment (segment extending from either sample well 41), whereby said first major surface further defines an associated group sample port (410 and group waste port (44) for each separation channel of said grouped pair of separation channels wherein each associated group sample port and group waste port are in fluid communication across said loading segment of a single

separation channel (Figure 4 inset) (this forming step is implied since all of the claimed elements to be formed are shown in Figure 4).

Mathies does not mention forming a first perimetrical edge segment extending along said first separation channel and a second perimetrical edge segment extending along said second separation channel

Zanzucchi discloses a method for forming a shaped capillary array electrophoresis chip having a first perimetrical edge segment extending along a first separation channel and a second perimetrical edge segment extending along the last separation channel in the chip (see module 148 in Figure 7B and the unlabeled module in Figure 10 and col. 6, ll.14-50).

It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the chip shown in Figure 4 of Mathies made of 4 modules (quadrants) each having a perimetrical edge extending along a first separation channel and a second perimetrical edge extending along a second separation channel as taught by Zanzucchi in the invention of Mathies because then several sets of separations may be performed simultaneously under different conditions. For example, the modules can each be made from a different substrate material (col. 2, ll. 24-27 in Mathies) and wells and channels can be configured in each module so that each module is appropriately suited for a different assay/analysis (col. 2, ll. 20-37 and col. 5, ll. 25-37 in Zanzucchi).

Addressing claim 24, in Mathies as modified by Zanzucchi each separation channel group extends in fluid communication from a common anode port. See col. 4:62-65. It would have been obvious to one with ordinary skill in the art at the time of the invention to reverse the cathode and anode in Mathies as modified by Zanzucchi if this will draw the charged analytes down the separation channels.

Addressing claim 25, Mathies discloses a method for forming a shaped capillary array electrophoresis chip comprising the steps of

providing a substantially planar substrate (40) having a first major surface (implied by Figure 4);

forming first and second converging elongate separation channels (42) in said first major surface (implied by Figure 4, which shows first and second converging channels as claimed);

Mathies does not mention forming a first perimetrical edge segment extending along said first separation channel and a second perimetrical edge segment extending along said second separation channel

Zanzucchi discloses a method for forming a shaped capillary array electrophoresis chip having a first perimetrical edge segment extending along a first separation channel and a second perimetrical edge segment extending along the last separation channel in the chip (see module 148 in Figure 7B and the unlabeled module in Figure 10 and col. 6, ll.14-50).

It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the chip shown in Figure 4 of Mathies made of 4 modules (quadrants) each having a perimetrical edge extending along a first separation channel and a second perimetrical edge extending along a second separation channel as taught by Zanzucchi in the invention of Mathies because then several sets of separations may be performed simultaneously under different conditions. For example, the modules can each be made from a different substrate material (col. 2, ll. 24-27 in Mathies) and wells and channels can be configured in each module so that each module is appropriately suited for a different assay/analysis (col. 2, ll. 20-37 and col. 5, ll. 25-37 in Zanzucchi).

As for having 46 converging channels in said first major surface between the first and second separation channels, although only 24 converging channels are shown in each perspective module in Figure 4 of Mathies, clearly this is only exemplary and a larger number of channels, such as 46, could be made in each module. Barring evidence to the contrary, such as unexpected results, having 46 channels in each module, when Mathies shows 24, is just effectively duplicating parts for multiplied effect, which has been held *prima facie* obvious. MPEP 2144.04 VI. B.

Final Rejection

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Nogueroles
Primary Examiner
AU 1753
April 20, 2005